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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,862	11/06/2001	Alexander Gaiger	14058-013520US	6155

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EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,862	GAIGER ET AL.	
	Examin r	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority und r 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Supplemental

The Office action mailed 9/30/2003 is incomplete. The following supplemental restriction requirement replaces the previous Office action mailed 9/30/2003.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-4, 8, 11 and 15, drawn to an isolated polynucleotide encoding a protein, and composition and kit containing the polynucleotide, classified in class 536, subclass 221.

II. Claims 2 and 11, drawn to an isolated polypeptide and a composition containing the polypeptide, classified in class 530, subclass 350.

III. Claims 5, 11 and 16, drawn to an antibody, and composition and kit containing the antibody, classified in class 530, subclass 388.1.

IV. Claim 6, drawn to a method for detecting the presence of a cancer via polypeptide, classified in class 435, subclass 7.1.

V. Claims 7 and 11, drawn to a fusion protein and composition containing the fusion protein, classified in class 435, subclass 69.7.

VI. Claim 9, drawn to a method of stimulating T cells specific for a tumor protein, classified in class 424, subclass 9.1.

VII. Claims 10-11, drawn to an isolated T cell population and composition containing the T cell population, classified in class 435, subclass 325

VIII. Claims12-13, drawn to a method for stimulating an immune response in a patient and the treatment of a cancer in a patient, classified in class 424, subclass 9.1.

IX. Claim 14, drawn to a method of determining the present of cancer via using nucleic acid hybridization, classified in class 435, subclass 6.

X. Claim17, drawn to a method for inhibiting the development of cancer, classified in class 424, subclass 9.1.

XI. Claims 18, 20-21, 27 and 30, drawn to an isolated polynucleotide, vector and host cell containing the polynucleotide, classified in class 536, subclass 22.1/325.

XII. Claims 19 and 27, drawn to an isolated polypeptide, classified in class 530, subclass 350.

XIII. Claims 22, 27 and 31, drawn to an isolated antibody, classified in class 530, subclass 388.1.

XIV. Claims 23, drawn to a method of detecting the presence of cancer via polypeptide, classified in class 435, subclass 7.1.

XV. Claims 24 and 27, drawn to a fusion protein, classified in class 435, subclass 69.7.

XVI. Claim 25, drawn to a method of stimulating T cell specific for a tumor protein, classified in class 424, subclass 9.1.

XVII. Claims 26 and 27, drawn to an isolated T cell population, classified in class 435, subclass 325.

XVIII. Claims 28-29, drawn to a method of stimulate an immune response in patient and the treatment of a cancer in a patient, classified in class 424, subclass 9.1

XIX. Claim 32, drawn to a method of inhibiting the development of a cancer in a patient, classified in class 424, subclass 9.1.

2. The inventions are distinct, each from the other because:

A. Inventions I-III, V, VII, XI-XIII, XV and XVII, and IV, VI, VIII, IX, X, XIV, XVI, XVIII and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products groups, I-III, V, VII, XI-XIII, XV and XVII are drawn to a polynucleotide or polypeptide or antibody or fusion protein or T cell population. Polypeptides and nucleic acids have distinct chemical structures and physical properties, the former composed of amino acids and the latter composed of nucleotides. Further, they have distinct utilities, such as use of nucleic acids in hybridization and use of proteins for enzymatic function. Antibody is composed of amino acid, but antibody has its special chemical structure and it is used in protein purification or immuno-assay. Fusion protein has its specific chemical structure as constructed and used in a specific way. T cell population can be used to produce antibody. Therefore, the above inventions are novel and unobvious over each other.

B. Among the products groups I and XI, they are drawn to an isolated polynucleotide, but each group comprises different nucleic acid sequences as claimed. They are distinct inventions.

C. Among the products groups II, and XII, they are drawn to an isolated polypeptide, but each group comprises different amino acid sequences as claimed. They are distinct inventions.

D. Among the products groups III and XIII, they are drawn to an antibody, but the antibody of each group has different specificity as claimed. They are distinct inventions.

E. Among the products groups V and XV, they are drawn to a fusion protein, but the fusion protein of each group has differently combined proteins as claimed. They are distinct inventions.

F. Among the products groups VII and XVII, they are drawn to a T cell population, but the T cell population of each group produces different antibodies as claimed. They are distinct inventions.

G. Inventions IV, VI, VIII, IX, X, XIV, XVI, XVIII and XIX are distinct, if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are the method groups IV, VI, VIII, IX, X, XIV, XVI, XVIII and XIX. Groups IV and XIV are drawn to a method of detecting the presence of cancer via polypeptide to detect the presence of a cancer in which each group uses different polypeptides as claimed, Groups VI and Group XVI are drawn to a method of stimulating T cell specific for a tumor protein, but each group uses different polynucleotides or polypeptides or antigens, Groups VIII and XVIII are drawn

to a method of stimulate an immune response in patient and the treatment of a cancer in a patient in which each group uses different polynucleotides or polypeptides or antibodies or fusion proteins or T cell populations as claimed, Group IX is drawn to a method of determining the present of cancer with polynucleotide, Groups X and XIX are drawn to a method of inhibiting the development of a cancer in a patient in which each group uses different polynucleotides or polypeptides or antibodies or T cell populations as claimed.

3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted.

A. If one of the group from group I-III, V and VII is elected then the following species election is also required to elect with a corresponding subject matter. These groups contain a composition claim 11 directed to the following patentably distinct species of the claimed invention a) polypeptide, or b) polynucleotide, or c) antibody, or d) fusion protein or e) T cell population.

B. If group VI is elected then the following species election is also required. Group VI is directed to the following patentable distinct species of the claimed invention: stimulating T cells with a) polynucleotide according to claim 2 or b) polynucleotides according to claim 1 or c) antigen-presenting cells according the claim 1.

C. If one of the groups from groups VIII and XVIII is elected then the following species election is also required. Group VIII and XVIII are directed to the following patentable distinct species of the claimed invention: stimulating an immune response in a patient or treating a cancer in a patient by administering to the patient a composition containing a) polypeptide,or b) polynucleotide, or c) antibodies, or d) fusion protein and or e) T cell population and antigen presenting cells.

D. If one of the groups from groups X and XIX is elected then the following species election is also required. Groups X and XIX are directed to the following patentable distinct species of the claimed invention: inhibiting the development of a cancer in a patient by incubating CD4+ and/or CD8+ T cells isolated from a patient with a) polypeptide according to claim 2 or 19, b) polynucleotide according to claim 1 or 18, c) antigen presenting cells that express a polypeptide of claim 2 or claim 19.

E. If one of the group from groups XI-XIII, XV and XVII is elected then the following species election is also required to elect with a corresponding subject matter in the composition. These groups contain a composition claim 27 directed to the following patentably distinct species of the claimed invention a) polypeptide, or b) polynucleotide, or c) antibody, or d) fusion protein or e) T cell population.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. These claims are generic to a plurality of disclosed patentably distinct restriction groups comprising different SEQ ID NOs. Applicant is required under 35 U.S.C. 121 to elect no more than 1 disclosed nucleic acids or amino acid even though this requirement is traversed.

Should applicant traverse on the ground that some or all of the different nucleic acids are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the nucleic acids to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between products claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with

an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung J.T
October 20, 2003

ETHAN WHISENANT
PRIMARY EXAMINER